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October 14, 2019

VIA ELECTRONIC MAIL

Honorable Freda L. Wolfson, Chief Judge
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Re: *In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation (MDL No. 2738)*

Dear Chief Judge Wolfson:

The PSC replies to J&J's letter (ECF No. 10724) regarding the recent *New England Journal of Medicine* publication guidelines that J&J claims the PSC "grossly misinterprets."

Central to the *Daubert* cross-motions is the role of statistical significance (SS) or, more specifically, the role of "significance testing" in assessing the epidemiology evidence. To put the NEJM's 2019 revised guidelines in context to those cross-motions, the PSC's experts (exemplified by Dr. McTiernan whose hearing testimony J&J largely ignores) argued SS is one of several *tools* epidemiologists use to assess association and consistency. Specifically, the PSC's experts opined that SS must be considered **along with** risk estimates and confidence intervals, and must also be informed by professional judgment. In other words, SS is not the be all and end all consideration that determines whether causation exists.

To support its attack on this methodology, J&J produced expert reports arguing that SS is a **required test** that must exist for both association and consistency. Midway through the expert discovery period, however, the scientific community weighed in. In March 2019, the *American Statistical Association* (ASA) devoted an entire volume of its Journal to the role of "p-values" and "statistical significance." In editorials which summarized these publications, the ASA reinforced its 2016 Statement on SS¹ admonishing scientists to "never" do what J&J and its experts have done in this case, *i.e.*, conclude that "two studies conflict because one had a

¹ Wasserstein & Lazar, *The ASA's Statement on p-Values: Context, Process, and Purpose*, 70 Am. Statistician 129 (2016), ECF No. 9914, Ex. 142.

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statistically significant result and the other did not.”² While Dr. Diette’s hearing testimony softened his prior position in light of the ASA statement, he nonetheless maintained that leading medical journals still use SS as the *test* for association, wrongly suggesting that it is the singularly most important consideration.

The NEJM’s July 2019 Guidelines undermine Dr. Diette’s suggestion that the ASA has been engaging in an interesting academic debate with no practical application to the interpretation of scientific evidence. In revising its publication guidelines, the NEJM, relying on the ASA’s 2016 and 2019 statements, expressed its own opinion and concern for the “the overuse and misinterpretation of significance testing and P values.”³ It acknowledged (as the PSC’s experts do) that P values and statistical significance still play a role and are not eliminated altogether, but the NEJM emphasized (as the PSC’s experts also do) that “evidence about... harms...*should include both point estimates and their margins of error.*”⁴ NEJM’s overall purpose in modifying its publication guidelines is most critical in assessing the *Daubert* cross-motions in this case – avoiding “concluding that the null hypothesis is false when in fact it is true.” Taken as a whole, NEJM’s actions **support** the methodology used by Drs. McTiernan, Siemiatycki, Moorman, Smith-Bindman and Singh and — in NEJM’s own words — **rebut** the erroneous misconception employed by Drs. Diette, Ballman and Merlo, who would use “P values or confidence intervals as a bright-line marker for a conclusion or a claim.”⁵

The PSC appreciates the opportunity to reply to J&J’s letter and submits that it is J&J who “misinterprets” the NEJM’s guidelines, just as its own experts grossly misinterpreted the scientific methodology for assessing association and consistency.

Respectfully submitted,

/s/ Michelle A. Parfitt
Michelle A. Parfitt

/s/ P. Leigh O’Dell
P. Leigh O’Dell

cc: All Counsel

² Amrhein, Greenland, & McShane, *Retire Statistical Significance*, 567 *Nature* 305, 306 (2019), ECF No. 9914, Ex. 138; Ronald L. Wasserstein, et al., *Moving to a World Beyond “ $p < .05$ ”*, 73 *The American Statistician* 1 (Supp. 1 2019), ECF No. 9914, Ex. 137.

³ NEJM at 285

⁴ *Id.* at 286

⁵ *Id.*